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Laparoscopic Repair of Inguinal Hernia Using Surgisis Mesh and Fibrin Sealant

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ABSTRACT

Objective: We tested the hypothesis that laparoscopic inguinal herniorrhaphy using Surgisis mesh secured with fibrin sealant is an effective long-term treatment for repair of inguinal hernia. This case series involved 38 adult patients with 51 inguinal hernias treated in a primary care center.

Methods: Between December 2002 and May 2005, 38 patients with 45 primary and 6 recurrent inguinal hernias were treated with laparoscopic repair by the total extraperitoneal mesh placement (TEP) technique using Surgisis mesh secured into place with fibrin sealant. Postoperative complications, incidence of pain, and recurrence were recorded, as evaluated at 2 weeks, 6 weeks, 1 year, and with a follow-up questionnaire and telephone interview conducted in May and June 2005.

Results: The operations were successfully performed on all patients with no complications or revisions to an open procedure. Average follow-up was 13 months (range, 1 to 30). One hernia recurred (second recurrence of unilateral direct hernia), indicating a 2% recurrence rate.

Conclusions: Laparoscopic repair of inguinal hernia using Surgisis mesh secured with fibrin sealant can be effectively used to treat primary, recurrent, direct, indirect, and bilateral inguinal hernias in adults without complications and minimal recurrence within 1-year of follow-up.

Key Words: Inguinal hernia, Laparoscopy, TEP repair, Surgisis mesh, Fibrin glue.

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INTRODUCTION

Laparoscopic hernia repair using the totally extraperitoneal (TEP) approach is an effective technique of groin hernia repair with recurrence rates similar to those of open mesh techniques.[1–3] Stapling the mesh to avoid displacement and reduce recurrence risk has long been thought essential to effect satisfactory long-term results, although some data suggest that mesh fixation using tacks or staples is unnecessary.[4,5]

Mesh fixation using atraumatic means was first described by Jourdan and Bailey[6] in 1998 using cyanoacrylate glue. More recently, fixation using fibrin sealant has been described with positive results in animal models[7] and in humans.[5] Fixation using glue decreases the time of the procedure and minimizes the risk of certain complications, such as nerve entrapment, osteitis pubis, and hematoma.[4,5,7] Recently, a significant decrease in the rate of postoperative chronic pain with glue fixation compared with pain with tack staples was also reported.[5]

Surgisis IHM mesh (Cook Surgical, Bloomington, IN), a biologic hernia graft material composed of purified porcine small intestinal submucosa (SIS), was first introduced to the United States market as an alternative to synthetic mesh materials. This mesh, composed of extracellular matrix collagen, fibronectin,[8] and associated glycosaminoglycans[9] and growth factors,[10,11] has been extensively investigated in animal models[12–14] and used clinically in multiple surgical procedures, including contaminated ventral hernia repair[15,16] and inguinal hernia repair.[17,18] Its use in laparoscopic repair of inguinal hernia has been limited, and its compatibility with fibrin glue in these procedures has not been reported.

The objective of the current study was to evaluate the effectiveness of laparoscopic repair of inguinal hernia using Surgisis mesh secured with fibrin sealant in patients who had undergone TEP. Postoperative complications, pain duration after surgery, narcotic use, and time to return to work were recorded, and frequency of long-term pain and hernia recurrence were also assessed.

METHODS

Between December 2002 and May 2005, all patients presenting with inguinal hernia who were considered candi-

dates for laparoscopic repair were offered and given this procedure. Patients were excluded if they were not candidates for a general anesthetic or had prior lower abdominal surgery. Information from the charts of all patients giving informed consent and undergoing laparoscopic mesh placement with Surgisis was included in this study. Between December 2002 and May 2005, 51 inguinal hernias (femoral, bilateral, and recurrent included) in 38 patients were repaired using Surgisis mesh secured with fibrin sealant. All operations were performed by a single surgeon, and all operations were performed with the patient under general anesthesia without antibiotic prophylaxis. Hernias were classified as either primary or recurrent, and of a direct or indirect nature.

Operative Technique

The 2 components of the fibrin sealant (Tisseel, Baxter Healthcare Corporation, Glendale, CA) were reconstituted according to the manufacturer's instructions at the initiation of surgery. Patients were placed in the supine position and general endotracheal anesthesia was induced. A Foley catheter was inserted. The patient's entire abdomen was prepped with Betadine and block draped. A curvilinear incision was made near the umbilicus and carried down to the anterior rectus sheath, which was doubly grasped, elevated, and incised, entering the rectus sheath. The rectus muscles were retracted laterally, exposing the posterior rectus sheath. A peritoneal dissection balloon trocar (PDB-1, US Surgical, Norwalk, CT) was inserted and guided by manual and videoscopic guidance down to the level of the pubis where it was inflated and left inflated for several minutes for tamponade effect. It was then deflated, removed and replaced with a structural balloon trocar.

Pneumopreperitoneum was instituted under direct vision. Two, 5-mm trocars were placed in the middle hypogastrium, one suprapubically and the second midway between the pubis and the umbilicus. Cooper's ligament was identified, as were the cord structures and inferior epigastric vessels. The cord structures were skeletonized, and the hernia sac was reduced off the internal ring down to the level of the peritoneum.

A vertical line was drawn down the long axis of the Surgisis mesh by using a surgical marker to assist mesh orientation during the procedure. A rolled piece of Surgisis ES (7 cm x 10 cm) or Surgisis IHM (8 cm x 13 cm or 10 cm x 15 cm) was placed through the preperitoneum, unfurled, and placed, uncut, over the myopectinate orifice after soaking the mesh in saline for 10 minutes to 15 minutes. The 2 solutions of the fibrin sealant were drawn into separate syringes, which were then fitted into the laparoscopic applicator, Duplocath 35 M.I.C. (Baxter AG, Vienna, Austria). Once the mesh was deployed in the position desired, it was secured to the pubic bone (Cooper's ligament) in the midline, the lacunar ligament, laterally, and superiorly into the transversalis fascia with the fibrin sealant, which was allowed to set for several minutes. The posterior aspect of the matrix repair was then held in place as the pneumopreperitoneum was released under direct vision, observing the peritoneum to obtain its desired position relative to the matrix repair. All trocars were then removed. The skin incisions were closed with Dermabond skin adhesive (Ethicon, Somerville, NJ). Patients were then removed to the recovery room.

Patient demographic data (age, sex, and history of alcohol and tobacco use), postoperative complications, pain duration after surgery, narcotic usage (# of doses of Percocet 5/325 taken postoperatively), and time to return to work were recorded. Postoperative visits were performed at 2 weeks and 6 weeks. In May to June 2005, patients were asked to complete an open-ended, free-form questionnaire to further assess the frequency and persistence of any long-term pain. Recurrence was also assessed at this time by directly contacting the patients and asking them if they had seen any evidence of hernia recurrence or had concerns that their hernia had recurred. They were also asked specifically if they had seen another physician for a new hernia. Patients were only examined for recurrence at follow-up if they were unable to verbally express with certainty whether or not their hernia had recurred.

RESULTS

Of the 38 patients, 35 were men and 3 were women. Their average age was 49 years, and the majority were nonsmokers. Of the 51 hernias repaired, 45 were primary and 6 were recurrent. Most hernias (43, 84.3%) were classified as indirect. Demographic data and hernia classification are displayed in **Table 1**.

All patients could care for themselves within a day of surgery. Immediately following surgery, patients on average took 7 days off from work, though 21 patients (55%) rested for less than a week **(Table 2)**. One patient who had undergone bilateral hernia repair was off work for 4 weeks. Short-term pain associated with the procedure generally subsided completely within 3 days to 4 days, though 1 patient complained of postoperative pain for 2 weeks, which was controlled by a narcotic prescription in which 28 doses were used. Follow-up examination 2 weeks after the surgery revealed no swelling or localized

Table 1.
Patient Demographic Data and Hernia Classification

Characteristic	Patients (n = 38)
Age, mean years (range)	49 (24–82)
Male/Female	35/3
Smoke (Y/N/Not Available)	7/23/8
Alcohol (Y/N/Not Available)	11/15/12
Hernia type	
Primary (%)	45 (88.2)
Recurrent (%)	6 (11.8)
Patient Hernia Number	
Unilateral (%)	25 (65.8)
Bilateral (%)	13 (34.2)
General Hernia Classification	
Direct (%)	7 (13.7)
Indirect (%)	43 (84.3)
Pantaloon (%)	1 (2.0)

Table 2.
Follow-up Variables

Characteristics	Number
Pain Duration, d ± SD	3.2±3.6
Narcotic Usage, # ± SD	7±10
Return to Work, d ± SD	7±6
≤5 d	21
>10 d	9

abdominal pain, and the patient was allowed full activity and returned to work.

Postoperative complications were minor and generally expected as a consequence of surgery **(Table 3)**. Mild cord or canal swelling, or both, following the procedure was the most common complaint. In no patient was the degree of swelling judged as severe or necessitating intervention. Mild to moderate orchitis was noted in 3 patients (7.9%) following surgery, as were 2 cases of hematoma (5.3%) and 1 suspected case of seroma (2.6%) that resolved without intervention. Two patients (5.3%) presented with mild fever and localized pain and swelling following surgery. Ciprofloxacin was given for suspected infection, and both patients eventually resolved without further intervention.

Three patients (7.9%) reported frequent chronic pain 12 months to 18 months postoperatively. Two of these patients had bilateral indirect hernia repairs and are 12 months and 18 months postoperative without recurrence. The third patient had a repair of a recurrent direct hernia; this patient is 12 months postoperative, and the hernia has again recurred. This is the only recurrence (2%) noted in this series, with an average follow-up of 13±6 months (range, 1 to 30).

Table 3.
Postoperative Complications

Complication	Number
Chronic Persistent Pain	3
Orchitis	3
Hematoma	2
Infection	2
Cord/Canal Edema	
None	22
Mild	15
Moderate	1
Severe	0
Seroma	1
Recurrence	1

DISCUSSION

Surgisis is a new biologic mesh for hernia repair that gradually incorporates into the patient's body wall and forms a strong repair consisting entirely of organized fibrovascular tissue without the persistence of a foreign body that can lead to eventual infection. In animal models, the mesh is gradually replaced by organized connective tissue and can no longer be detected after approximately 6 months, even though the strength of the repair is maintained at least as long as up to 2 years.[13,19] To date, its compatibility with fibrin sealant in laparoscopic inguinal hernia repair has not been reported. In this series, we evaluated the effectiveness of laparoscopic repair of inguinal hernia using Surgisis mesh secured with fibrin sealant in patients who had undergone TEP.

Fixation of mesh using glue has several advantages over tacks or staples. Although we didn't measure the operative time, others have reported that the use of glue decreases the time of the procedure and minimizes the risk of certain complications, such as nerve entrapment, osteitis pubis, and hematoma.[4,5,7] A significant decrease in the rate of postoperative chronic pain with glue fixation as compared with tack staples has also been reported.[5]

In the current series, 3 (7.9%) patients reported chronic pain 12 months to18 months following their procedures. Although this incidence of chronic pain is higher than reported elsewhere for TEP procedures in which the mesh was affixed with fibrin sealant (4.5%),[5] it is still lower than the 9.2% to 14.7% pain incidence reported when staples were used,[5,20] and much less than up to 62% chronic pain reported with open repair techniques.[21,22] However, in other reports where Surgisis mesh was used in Lichtenstein repair of inguinal hernia, incidence of pain was lower compared with pain from polypropylene mesh.[17,18] Recent literature points to the emergence of "meshomas" secondary to placement of prosthetic mesh in hernia repairs as a source of chronic pain.[23] This phenomenon, due to nonfixation, insufficient fixation, or insufficient dissection, results in folding and wrinkling of the mesh, a process that continues until the mesh is wadded up into a ball. The mechanical pressure of this abrasive material on the adjacent tissues may lead to chronic postsurgical pain that is only relieved if the mesh is removed. Because Surgisis mesh is a biologic material that completely remodels, the risk of forming a foreign-body meshoma is minimized with this material, and the ensuing loss of repair integrity is eliminated.

There were no reports of osteitis pubis, nerve or vascular injury, or bowel lesions in this series. We noted 2 cases of hematoma (5.3%), 1 seroma (2.6%), and 3 mild cases of orchitis (7.9%), all of which resolved without intervention. These incidences compare favorably with those reported by Topart et al,[5] who noted seroma in 12% of cases and hematoma in 4.5% of cases. Only one recurrence was reported, at 12 months postoperative, and this was in a patient who was treated for a recurrent direct hernia. Because patients were asked to self-examine themselves and were only asked to return to the clinic if they were equivocal about recurrence, it is possible that asymptotic recurrences were missed.

Surgisis mesh has been shown to gradually remodel into native body wall over a span of 6 months and also that the strength of the repair remains after as long as 2 years.[13,19] Even though the current results are preliminary and the average follow-up was limited to 13 months, it is noteworthy that the combination of fibrin glue and a biologic mesh can be effective in TEP repair out to a follow-up time that exceeds the time it takes for the mesh to be completely replaced by the patient's own tissues. Even though tissue biopsies were not obtained to show that the mesh and glue were completely remodeled, the animal data suggest that the only tissue remaining at the 13-month time-point would be entirely patient tissue. Longer-term follow-up in other human case series has generally supported this hypothesis.[15,24]

CONCLUSIONS

Laparoscopic repair of inguinal hernia using Surgisis mesh secured with fibrin sealant can be effectively used to treat primary, recurrent, direct, indirect, and bilateral inguinal hernias in adults without unexpected complications and minimal incidence of recurrence in a short-term follow-up. Complications noted in this series were typical of the operation, similar in incidence to those rates reported in the literature, and resolved without surgical intervention. The 2% short-term recurrence rate is promising and indicates that fibrin glue can be used effectively to secure biologic mesh, such as Surgisis, in laparoscopic inguinal hernia repair using the TEP technique. Longer term follow-up is necessary to fully establish the efficacy of this technique.

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